Biodiversity Rules and Regulations 2023

Contents

CHAPTER 1
PRELIMINARY

Title

1. This Rules is called the Biodiversity Rules and Regulations of Bhutan, **2023**.

Commencement

2. This Rules shall come into force on the **26th** Day of the **12th** Month of the Bhutanese Calendar corresponding to the **16th** Day of the **2nd** Month of 2023.

Extent

3. The Rules extend to the whole of the Kingdom of Bhutan.

Objectives

4. The objectives of this Rules is to implement the provisions of the Biodiversity Act of Bhutan, 2022.

CHAPTER 2

INSTITUTIONAL ARRANGEMENT

Competent National Authority

5. The Competent National Authority shall consist of the following members as per section 13 of the Act:

   (1) Minister, the Ministry of Agriculture and Livestock, Chairperson;

   (2) Secretary, Ministry of Agriculture and Livestock, Vice Chairperson;

   (3) National Environment Commission, Member;

   (4) Head, Department of Forests and Park Services, Ministry of Energy and Natural Resources, Member;

   (5) Head, Department of Agriculture, Ministry of Agriculture and Livestock, Member;

   (6) Head, Department of Livestock, Ministry of Agriculture and Livestock, Member; and

   (7) Head, the National Biodiversity Centre, Member Secretary.

6. The concerned member specified under section 5 of this Rules shall nominate an alternate member to the Competent National Authority and the alternate member shall exercise the rights to represent the Competent National Authority.

Rules of Procedures of the Competent National Authority

7. The Competent National Authority shall exercise all the functions prescribed under section 14 of the Act.

8. In accordance with section 15 of the Act, the Competent National Authority shall:

   (1) Meet biannually and as and when required.

   (2) The meeting shall require a minimum quorum of two-third members.

   (3) The decision of the Competent National Authority shall be based on simple majority.

9. The Chairperson may authorize the Vice Chairperson to conduct the meeting, if the Chairperson is not available for meeting on the scheduled date.

10. The Member Secretary shall prepare an annual schedule of meeting in consultation with the Chairperson and share it with the members at the beginning of the financial year.

11. The meeting shall be conducted as per the schedule except in inevitable circumstances where the Chairperson has altered the meeting date.

12. The Member Secretary shall provide prior information within five working days to the members for any change in the meeting schedule.

13. The Member Secretary shall circulate the agenda and related documents for the meeting prior to five working days from the date of meeting.

14. The Member Secretary shall keep record of all the proceedings of the meeting and maintain proper documentation including signed copy of resolution.

15. The Member Secretary may propose for an *ad-hoc* meeting to the Competent National Authority when it has received an access proposal that requires immediate intervention.

Directives to the National Focal Point

16. In accordance with section 14 (4) of the Act, the Competent National Authority shall provide policy directives to the National Focal Point on the implementation of the Act and its Rules.

National Focal Point

17. The National Biodiversity Centre shall be the National Focal Point and carry out the functions specified in section 17 of the Act.

National Clearing House Publishing Authority

18. In accordance with section 17 (2) of the Act, the National Focal Point as a clearing house publishing authority shall publish the information related to access and benefit sharing at the Access and Benefit Sharing Clearing House through online platforms.

19. The National Focal Point shall share the information upon approval of the Competent National Authority.

20. The National Focal Point under section 19 of this Rules shall share the following information on:

    (1) legislative, administrative and policy measures on access and benefit sharing;

(2) information on the Competent National Authority and National Focal Point;

(3) details on compliance document including Prior Informed Consent, Mutually Agreed Terms, Convention on International Trade in Endangered Species permit, Standard Material Transfer Agreement, subject matter of genetic resources, utilization and conditions on third-party transfer;

(4) information on access and benefit sharing checkpoints;

(5) information on Bhutan Biodiversity Portal and Clearing House Mechanism;

(6) methods and tools developed to monitor genetic resources; and

(7) non-compliance information

National Repository

21. In accordance with section 17 (3) of the Act, the National Focal Point shall be the repository for plant and animal gene bank, traditional knowledge associated with biological resources, national herbarium, *ex-situ* living plant collection, fungi, microbial and invertebrate genetic resources and other biological resources.

22. The National Focal Point shall identify relevant agencies dealing with the traditional knowledge associated with biological resources for documentation, preservation and the identified relevant agency shall share a copy of the documentation to National Focal Point for maintaining record in the national repository.

Taxonomy and systematic study of biodiversity

23. In accordance with section 17 (12) of the Act, the National Focal Point shall conduct and facilitate taxonomic and systematic studies on biodiversity in collaboration with relevant stakeholders.

24. Any legal or natural person conducting taxonomic and systematic studies on biodiversity shall submit the information and specimens thereof to the National Focal Point to be maintained in the National Repository.

Reporting of offense

25. The National Focal Point shall compile an offense record received from the enforcement officers designated under section 127 of this Rules and submit the report to the Competent National Authority annually.

National Biodiversity Strategies and Action Plan

26. In accordance with section 17 (15) of the Act, the National Focal Point shall coordinate implementation of the National Biodiversity Strategies and Action Plan.

CHAPTER 3

CONSERVATION AND SUSTAINABLE USE

Ex-situ conservation

27. In accordance with section 22 of the Act, the National Focal Point shall prioritize species for:

    (1) live ex-situ conservation in consultation with relevant agencies based on the following criteria:

        (a) global or national conservation status of threatened species; or

        (b) species potential for research and development at commercial scale.

    (2) gene bank for:

        (a) food and nutrition security;

        (b) conservation of traditional varieties of crops and local breeds of animal;

        (c) conservation of neglected and under-utilized species;

        (d) conservation of native species; or

        (e) conservation of microbes and fungi.

Invasive alien species

28. In accordance with section 23 of the Act, the National Focal Point shall in consultation with relevant stakeholders:

    (1) coordinate documentation of invasive alien species;

    (2) develop national management strategies for invasive alien species; and

    (3) publish and share a list of invasive alien species with pictorial guide and identification description to regulatory authorities for prohibition from import annually or as and when required.

29. The enforcement officers at the first point of entry shall upon detection of invasive alien species, forward to the relevant regulatory authority as per the guideline and standard operating procedure. In the event, the regulatory authority or enforcement officer is not able to identify the species, it shall seek the support of the National Focal Point for accurate identification.

Restricted genetic resources

30. In accordance with section 26 of the Act, genetic resources of the species:

    (1) listed under Schedule I of the Forest and Nature conservation laws shall not be accessed except for scientific research to promote conservation; and

    (2) listed under Schedule II and III of the Forest and Nature Conservation laws shall be accessed for scientific research to promote conservation; or commercial utilization with exception to wild fauna.

31. In accordance with section 27 and 28 of the Act, notwithstanding the prevailing customary practice, the Competent National Authority may, on the recommendation of the National Focal Point, grant or limit or restrict access to genetic resources for national importance to:

    (1) conserve genetic resources of threatened species;

    (2) utilize genetic resources of high economic value; or

    (3) any other situation considered as necessary by the Competent National Authority.

CHAPTER 4

A SUI GENERIS SYSTEM FOR THE PROTECTION OF PLANT VARIETIES

Application Procedure for Plant Variety Protection

32. Any applicant may file an application for plant variety right protection to the National Focal Point as per the format prescribed in ***Form I*** of this Rules.

Examination

33. The National Focal Point shall assess the application to examine the variety through conduct of examination for the criteria specified under section 30 to 34 of the Act in collaboration with relevant agencies.

34. The examination of the plant variety shall be conducted based on the following methods:

    1) Documentation;
    2) On-site inspection;
    3) Growing test; or
    4) Any other methods relevant for examination.

35. The National Focal Point shall develop standards and technical guidelines for the examination methods prescribed under section 33 and 34 of this Rules.

Publication for Opposition

36. The National Focal Point shall publish the results of the test carried out under section 33 and 34 of this Rules in the public domain for validation of the variety protection for 90 days as per the format prescribed in ***Form II*** of this Rules.

37. In the event of any opposition to the published results, the National Focal Point shall carry out the reassessment on the assignment of the right.

38. The National Focal Point shall submit the assessment results to the Competent National Authority for grant of the variety right if no opposition is made on the result.

Grant or Rejection of Plant Variety Right

39. The Competent National Authority shall grant certificate of registration of plant variety right based on the report of the National Focal Point and inform the applicant accordingly.

40. The Competent National Authority may reject protection for plant variety based on the assessment report of the National Focal Point and inform the applicant accordingly.

41. The applicant may appeal to the Competent National Authority through National Focal Point in the event of rejection within 10 working days of the issuance of the decision.

Assignment of Application or Restitution of the Title

42. Any person intending to file for reassignment or restitution of the title of variety rights under section 38 and 39 of the Act, respectively, shall be filed to the National Focal Point as per the format prescribed in ***Form II*** of this Rules.

43. The National Focal Point shall submit the report of assessment on the reassignment or restitution of title within 30 working days from the date of receipt of the application to the Competent National Authority.

44. The Competent National Authority shall conduct a meeting within five working days from the date of submission of the report by National Focal Point to reassign or restitute the title of variety right based on the assessment report of the National Focal Point.

Variety Rights Registration Certificate Renewal

45. The applicant shall be required to renew the variety rights certificate after five years of the grant of the certificate with payment of Nu. 500 as renewal fee except for farmers.

Lapse of rights protection

46. In the event the applicant fails to renew the variety rights certificate as per section 45 of this Rules, the rights protection will lapse automatically.

Cancellation of Breeders Right

47. The National Focal Point shall monitor the variety protection granted as per the purity maintenance and breeding standards. In the event of non-compliance to the standards, the Competent National Authority shall cancel the breeders right based on the recommendation of the National Focal Point.

48. The National Focal Point shall carry out the monitoring of the protected plant variety based on the following prescription:

    (1) Biannual crops: Once in three to five years; and
    (2) Perennial crops: Once in five to 15 years.

49. The Competent National Authority shall notify the breeder on the decision of the cancellation along with the monitoring report within two working days from the date of the meeting, if there is cancellation in accordance with section 47 of this Rules

50. The breeder may appeal to the Competent National Authority within 10 working days from the date of issue or cancellation of the breeders' rights by the Competent National Authority.

Certificate of Origin

51. The National Focal Point may issue the certificate of origin of the plant variety on the instruction of Competent National Authority upon fulfillment of the following:

    (1) determination of the source of seed variety;
    (2) documentation of the variety by the National Focal Point; and
    (3) validation of information on the variety by the National Focal Point from the relevant agencies.

CHAPTER 5
ACCESS TO GENETIC RESOURCES

Application for access to genetic resources

52. Access to genetic resources shall be obtained through one of the procedures specified in section 58 of the Act.

Access Proposal

53. In accordance with section 59 of the Act, an applicant shall submit an access proposal to the National Focal Point in the format prescribed in ***Form III*** of this Rules.

Processing fees

54. In accordance with sections 59 and 88 of the Act, the applicant shall make non-refundable payment as application processing fee during the submission of access proposal to grant access to genetic resources and actualization phase to the National Focal Point as follows:

    (1) 500.00 US Dollars, if an applicant is an international entity; or

    (2) Equivalent fee in Ngultrum calculated at prevailing US Dollar exchange rate on the day of application by Bhutanese entity; or

    (3) Any currency agreed in bilateral trade agreements between countries at the equivalent fee of 500.00 US Dollar.

55. The applicant intending to access genetic resources through Material Transfer Agreement and Standard Material Transfer Agreement shall be exempted from payment of the processing fee.

56. In accordance with section 64 of the Act, the National Focal Point may recommend exemption from payment of processing fee to the Competent National Authority for access to genetic resources in a situation:

    (1) where Access and Benefit Sharing is only option for economic revival at national level; or

    (2) where genetic resources are used for countering pandemic.

Review of Access Proposal

57. The National Focal Point shall conduct preliminary resource assessment of particular genetic resources in consultation with the relevant stakeholders upon receipt of application for grant of access.

58. In accordance with section 60 of the Act, the National Focal Point shall review access proposals to ensure completeness of an access application and make an assessment of the access proposal as per the guidelines for assessment.

59. The National Focal Point shall submit the assessment report to the Competent National Authority for approval or rejection.

60. In accordance with section 60 and 61 of the Act, the National Focal Point upon assessment of access proposal and based on the intended use of genetic resources provide recommendation to the user on suitable access procedures from the options specified under section 58 of the Act within five working days from the date of receipt of an application.

61. In accordance with section 63 of the Act, the Competent National Authority based on the recommendation of the National Focal Point may approve or reject the access to genetic resources, and the National Focal Point shall communicate the decision within five working days of the Competent National Authority meeting.

Prior Informed Consent

62. In accordance with section 66 of the Act, the National Focal Point shall seek Prior Informed Consent of the providers of genetic resources or holders of associated traditional knowledge in the format prescribed in ***Form IV*** of this Rules.

Relationship with other Permits

63. In accordance with sections 67 and 68 of the Act, the National Focal Point may assist the User to obtain the following permits or clearance, where applicable:

    (1) Clearance or permit from the Department of Forests and Park Services for collection of genetic resources from the State Reserved Forest Land;

(2) Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permit for transfer of materials;

(3) Phytosanitary or Zoosanitary certificate from the Bhutan Food and Drug Authority for transfer of materials;

(4) Any other clearance or permit as may be required with change in legal requirement.

Resource Sustainability Assessment

64. In accordance with section 69 of the Act, the National Focal Point shall carry out resource sustainability assessment in consultation with the relevant stakeholders if there is a need to carry out such assessment, *inter-alia* on the following:

(1) availability of the resource;

(2) magnitude of the activity and size of the intervention area;

(3) impacts on biological diversity;

(4) environmental impacts;

(5) such other matters as the National Focal Point may consider necessary.

65. In accordance with section 70 of the Act, the User shall pay the actual cost for the conduct of assessment.

General Procedure

66. The User shall comply with the general procedures prescribed under section 71 to section 76 of the Act to enter into Scoping Agreement or Access and Benefit Sharing Agreement.

Scoping Agreement

67. In accordance with sections 17 (5) and 77 of the Act, the National Focal Point on behalf of the providers of genetic resources shall, upon the approval of the negotiated terms by the Competent National Authority, execute a Scoping Agreement with the User for the initial exploratory research.

68. In accordance with section 78 of the Act, the National Focal Point and users shall execute Standard Scoping Agreement as prescribed in ***Form V*** or negotiated contract.

69. The User shall be granted access to a maximum of one genetic resource under one Scoping Agreement. In the event, there is a request for more than one genetic resource, it shall be approved by the Competent National Authority.

70. In accordance with section 82 of the Act, a User shall submit a third-party access proposal in the format prescribed in ***Form VI*** for negotiating an Access Benefit Sharing Agreement, upon approval from the Competent National Authority; if a third-party intends to undertake product development or commercial activities.

Commitment fee

71. In accordance with section 80 of the Act, a Scoping Agreement shall be conditional on the payment of non-refundable commitment fee to the National Focal Point as follows:

    (1) 5000.00 US Dollars, if an applicant is an international entity; or

    (2) equivalent fee in Ngultrum calculated at prevailing US Dollar exchange rate on the day of application by Bhutanese entity; or

    (3) Any currency agreed in the bilateral trade agreement between the countries at the equivalent fee of 5000.00 US Dollars.

72. In accordance with sections 86 and 88 of the Act, the User shall pay the non-refundable commitment fee prescribed under section 71 of this Rules during the execution of Access and Benefit Sharing Agreement, if the National Focal Point determines that the User may directly enter into Access and Benefit Sharing Agreement without execution of the Scoping Agreement.

Surrender of accessed genetic resources, research results and related information

73. In accordance with section 83 of the Act, a User not intending to enter the Access and Benefit Sharing Agreement or after termination of the Scoping and Access and Benefit Sharing Agreement, shall surrender the accessed genetic resources, research results and related information at their own cost within 30 working days after the termination of the Scoping Agreement to the National Focal Point.

Access and Benefit Sharing Agreement

74. In accordance with section 86 of the Act, the Provider and the Users may enter directly into a Standard Access and Benefit Sharing Agreement as prescribed in ***Form VII*** or negotiated contract between Provider and the User and the National Focal Point shall recommend under the following circumstances:

    (1) there is prior research conducted on the specific genetic resource by the User;

    (2) the research findings on particular genetic resource are already in public domain; or

    (3) the User comes with a prototype and product line from or for specific genetic resources.

75. The Access and Benefit Sharing Agreement shall be executed for individual genetic resources and products during the actualization phase for the genetic resources accessed under section 69 of this Rules.

Validity and Renewal

76. The validity of the Scoping Agreement and Access and Benefit Sharing Agreement shall be mutually agreed between the Provider and User.

77. The User shall apply to the National Focal Point for renewal of the Scoping Agreement and Access and Benefit Sharing Agreement, 90 Days before the expiry of the validity.

78. The National Focal Point shall seek the approval of the Competent National Authority to renew the Scoping Agreement and Access and Benefit Sharing Agreement.

79. The User shall pay non-refundable renewal fee to the National Focal Point upon approval of the renewal of the Scoping Agreement or Access and Benefit Sharing Agreement as follows:

    1) 250.00 US Dollars, if an applicant is an international entity;
    2) Equivalent fee in Ngultrum calculated at prevailing US Dollar exchange rate on the day of application for Bhutanese entity; or
    3) Any currency agreed in the bilateral trade agreement between the countries at the equivalent fee of 250.00 US Dollars.

Amendment

80. The Provider and User may mutually consent to amend the terms and conditions of the Scoping Agreement and Access and Benefit Sharing Agreement after seeking approval from the Competent National Authority.

81. The Providers and User upon mutual consent to amend the agreement shall negotiate on the amendment of existing or inclusion of new terms and conditions.

82. The amendment of agreement shall be effective only upon signing of addendum to the agreement by the parties.

83. The National Focal Point shall publish the non-compliance report by the Provider and User in the Access and Benefit Sharing Clearing House upon approval from Competent National Authority.

Certificate of Compliance

84. In accordance with section 89 of the Act, the Competent National Authority shall issue the Certificate of Compliance to the Users as per the format prescribed in ***Form VIII*** of this Rules.

Material Transfer Agreement

85. In accordance with section 91 of the Act, a User shall submit a request for Material Transfer Agreement to the National Focal Point in the format prescribed in ***Form IX*** of this Rules and the request for Material Transfer Agreement.

86. In accordance with section 93 of the Act, the National Focal Point shall determine whether the User qualifies for execution of Material Transfer Agreement under the purposes specified in section 92 of the Act.

87. The Competent National Authority shall delegate power to approve and execute Material Transfer Agreement to the National Focal Point within five working days from the date of receipt of the application and submit the report to Competent National Authority biannually.

88. The National Focal Point shall execute the Letter of Undertaking as per the format prescribed in ***Form XII*** for all the genetic resources which are exported for personal consumption and non-commercial research.

Access to plant genetic resources for food and agriculture

89. In accordance with section 94 of the Act, the National Focal Point shall carry out assessment and determine which genetic resources of released varieties for food and agriculture shall be based on the multilateral system.

90. The National Focal Point shall carry out the listing of plant genetic resources for food and agriculture in consultation with relevant agencies and the list shall be approved by the Competent National Authority.

Standard Material Transfer Agreement

91. In accordance with section 98 of the Act, a User shall submit a request for Standard Material Transfer Agreement to the National Focal Point in the format prescribed in ***Form X*** of this Rules.

92. The Competent National Authority shall delegate power to approve and execute Standard Material Transfer Agreement to the National Focal Point and submit the report biannually to the Competent National Authority.

Sample Transfer Certificate

93. In accordance with section 99 of the Act, the National Focal Point shall issue a sample transfer certificate as per the format prescribed in ***Form XI*** of this Rules.

CHAPTER 6

ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Documentation, Preservation and Protection

94. In accordance with section 101 and 102 of the Act, the National Focal Point shall carry out the inventory and documentation of traditional knowledge associated with genetic resources.

95. In accordance with section 104 of the Act, the Competent National Authority shall delegate the authority to National Focal Point to identify the relevant agencies or individual for inventory and documentation of traditional knowledge associated with genetic resources.

96. Any individual or Agency documenting traditional knowledge associated with genetic resources under section 105 of the Act shall require a prior informed consent from the provider of the traditional knowledge associated with genetic resources in the format prescribed in ***Form IV*** of this Rules in accordance with section 62 of this Rules.

National database on Traditional Knowledge

97. Any person intending to access the national database on traditional knowledge shall seek approval from the National Focal Point.

98. The person authorized to access the national database by the National Focal Point under section 97 of this Rules shall be required to sign a non-disclosure undertaking to safeguard traditional knowledge associated with genetic resources from misappropriation.

Community protocol

99. In accordance with section 108 of the Act, the National Focal Point shall support establishment of community-based group and facilitate development of community protocols; if necessary, on the following:

    (1) process of granting Prior Informed Consent;

    (2) formulation of Mutually Agreed Terms; and

    (3) fair and equitable sharing of benefits.

Providers of Traditional Knowledge associated with genetic resources

100. In accordance with section 110 of the Act, if a traditional knowledge associated with genetic resources is held by more than one community, the National Focal Point shall consider following criteria to engage particular community as the holder:

(1) evidence of traditional knowledge documented in the National Traditional Knowledge Database or any other available evidence of traditional knowledge;

(2) community with no Access and Benefit Sharing project;

(3) community with abundant genetic resources associated with the particular traditional knowledge; and

(4) socio-economic status of the community.

Access to Traditional Knowledge associated with genetic resources

101. A person seeking access to traditional knowledge associated with genetic resources shall submit an access proposal to the National Focal Point in the format prescribed in ***Form III*** of this Rules.

102. The access proposal for traditional knowledge associated with genetic resources shall comply with the requirement prescribed under Chapter 5 of this Rules.

Access and Benefit Sharing Agreement for traditional knowledge associated with genetic resources

103. In accordance with section 111 and 114 of the Act, the National Focal Point shall:

(1) negotiate an Access and Benefit Sharing Agreement with a User on behalf of the providers of traditional knowledge associated with genetic resources upon the approval of the access proposal by the Competent National Authority; and

(2) submit the outcome to the Competent National Authority for approval upon completion of the negotiation.

104. The Competent National Authority may recommend changes to an Access and Benefit Sharing Agreement at the time of approval.

105. The Provider shall, upon the approval of the negotiated terms by the Competent National Authority, execute an Access and Benefit Sharing Agreement with the User in the presence of the National Focal Point.

Third-Party Transfer

106. In accordance with sections 81 and 82 of the Act, if a User intends to transfer research results, accessed genetic resources or traditional knowledge associated with genetic resources to a third-party for product development and commercial utilization, the User shall submit the request to the National Focal Point with details prescribed in ***Form VI*** of this Rules.

107. The National Focal Point shall after reviewing information and on being satisfied that the applicant has fulfilled all the necessary requirements under section 106 of this Rules, submit recommendation to the Competent National Authority for decision within 30 days from the receipt of an application.

108. The Competent National Authority based on the recommendation of the National Focal Point shall render its decision within five working days after the conduct of the Competent National Authority meeting.

109. The National Focal Point upon approval for third-party transfer shall initiate or facilitate negotiation with the third party for accessed genetic resources or traditional knowledge associated with genetic resources.

110. The National Focal Point shall communicate to the User, if the application for third-party transfer is rejected by the Competent National Authority.

111. The third-party shall fulfill all the requirements prescribed under section 71 to 93 of the Act and section 52 to 103 of this Rules.

CHAPTER 7

FAIR AND EQUITABLE SHARING OF BENEFITS

Benefits

112. In accordance with section 118 of the Act, the benefit sharing shall comprise monetary or non-monetary benefits and the benefit shall be negotiated between the Provider and User.

113. The monetary benefit where appropriate may include:

(1) processing fee;

(2) commitment fee;

(3) renewal fee;

(4) payment of premium price;

(5) payment of commission from the sale of product;

(6) license fees in case of commercialization;

(7) contribution to be paid into the Bhutan Access and Benefit Sharing Fund;

(8) research funding;

(9) joint ownership of relevant intellectual property rights; or

(10) any other monetary benefits which may be negotiated between the parties.

114. The non-monetary benefit where appropriate may include:

(1) technology transfer and capacity building;

(2) institutional collaboration and cooperation;

(3) support in machinery, equipment and tools;

(4) infrastructure development;

(5) social recognition;

(6) admittance to *ex-situ* facilities of genetic resources and database; or

(7) any other mutually agreed non-monetary benefits.

Mutually agreed portion of the fund

115. In accordance with section 24 (3) of the Act, the Provider of the genetic resources cultivated on farmland or any private land by community-based groups may mutually agree to channel a certain portion of the monetary benefits into the Bhutan Access and Benefit Sharing Fund.

CHAPTER 8

BHUTAN ACCESS AND BENEFIT SHARING FUND

Bhutan Access and Benefit Sharing Fund

116. In accordance with section 129 of the Act, the National Focal Point as the administrator and manager of the Bhutan Access and Benefit Sharing Fund shall:

(1) submit financial statement to the Competent National Authority annually;

(2) facilitate auditing of the fund by internal as well as external auditors;

(3) invite project proposal to secure funding for implementation of activities allowed under section 130 of the Act; and

(4) report biannually on the progress of the activities funded to the Competent National Authority.

117. In accordance with section 129 of the Act, the Competent National Authority as the supervisor of the Bhutan Access and Benefit Sharing Fund shall approve the fund utilization proposal submitted by the National Focal Point.

118. The Competent National Authority shall authorize the utilization of the Bhutan Access and Benefit Sharing fund only after the total amount reaches Nu. 20 million.

Project proposal

119. Any entity, individual or community-based group interested to implement activities related to conservation and sustainable use of Bhutan's biodiversity and enhancement of rural livelihoods shall be eligible to submit project proposal to the National Focal Point and the assessment shall be carried out as per the Guidelines for administration and management of Bhutan Access and Benefit Sharing Fund.

Project monitoring and evaluation

120. The National Focal Point shall carry out monitoring and evaluation of the project activities and furnish report biannually to the Competent National Authority as per the Guidelines for administration and management of Bhutan Access and Benefit Sharing Fund.

CHAPTER 9

REGISTRY AND RECORDS

Registry

121. In accordance with section 134 of the Act, the National Focal Point shall maintain a registry containing details on:

(1) the name of the entity to whom access to genetic resources or traditional knowledge is granted;

(2) the date it was granted and validity;

(3) conditions agreed;

(4) information on the Access and Benefit Sharing Agreement;

(5) information on applications approved or declined and reason thereof;

(6) stock of genetic resources collected or dispatched;

(7) information on research results and genetic resources surrendered; and

(8) such other information as it may deem fit.

122. The National Focal Point shall maintain a registry of all the genetic resources dispatched from the country under the Material Transfer Agreement and Standard Material Transfer Agreement.

(1) detail of the applicant and recipient;

(2) the date it was granted;

(3) purpose of the genetic resources;

(4) destination;

(5) date of submission of research result;

(6) copy of final report; and

(7) conditions agreed.

Records

123. In accordance with section 135 of the Act, a User of genetic resource or associated traditional knowledge shall, as the case may be, maintain records on:

(1) research results;

(2) publication of research results;

(3) type and number of products developed, and sales record;

(4) details of the location where the genetic resource is kept;

(5) disposal of the accessed genetic resources; and

(6) such other information that may be considered necessary by the National Focal Point.

124. In accordance with section 136 of the Act, a User shall furnish a copy of the records maintained under section 123 of this Rules to the National Focal Point annually or as and when required.

125. In accordance with sections 137, 138 and 139 of the Act, the person or an agency who discovers new species, releases new crop variety, de-notifies seed variety or collects germplasm and genetic materials shall deposit the sample or specimen to the National Focal Point within 90 days from the date of discovery, release, de-notification or collection.

Disposal of genetic resources

126. In accordance with section 140 of the Act, the National Focal Point shall adopt following methods to dispose the returned genetic resources by the Users:

(1) store in the gene bank if the genetic resource has potential for regeneration;

(2) safe storage for potential future research and development; or

(3) safely dispose of the genetic resources as per the disposal guidelines.

CHAPTER 10

MONITORING AND ENFORCEMENT

Enforcement Officers

127. In accordance with section 142 of the Act, the National Focal Point with an approval from the Competent National Authority designate the following relevant officers as enforcement officers to monitor and regulate genetic resources at entry and exit:

(1) Royal Bhutan Police;

(2) Bhutan Food and Drug Authority;

(3) Department of Forests and Park Services; and

(4) National Focal Point.

128. The enforcement officer shall carry out the enforcement roles and responsibilities as per the Standard Operating Procedures (SoP) developed consultatively.

129. The enforcement officer specified under section 127 of this Rules at the entry and exit point shall forward all the cases apprehended to the following Departments or Agencies for imposition of fines and penalties as per the relevant laws:

(1) The Department of Forest and Park Services for any wild genetic resources;
(2) The Bhutan Food and Drug Authority for food and agriculture; or
(3) The National Focal Point for any violation specified under section 133 to 139 of this Rules.

Monitoring and tracking

130. In accordance with section 147 of the Act, the Competent National Authority shall on the recommendation of the National Focal Point designate the following agency as access and benefit sharing checkpoint:

(1) Department of Forests and Park Services;

(2) Bhutan Food and Drug Authority;

(3) Department of Revenue and Customs;

(4) National Focal Point; and

(5) Department of Media, Creative Industry and Intellectual Property.

131. The concerned checkpoint shall verify the information and document as per the Standard Operating Procedures (SoP) developed consultatively under this Rules.

132. The Competent National Authority may, on the recommendation of the National Focal Point, by written notification, designate additional check-points as and when considered necessary.

CHAPTER 11

OFFENSES AND PENALTIES

Unlawful access to genetic resources or associated traditional knowledge

133. In accordance with section 157 of the Act, the National Focal Point shall impose fines on any person who accesses or utilizes genetic resources or traditional knowledge associated with genetic resources for research and development, commercial or potential commercial purpose without executing the following agreements:

(1) Scoping Agreement shall be liable to a fine of Nu. 45,000.00 and compensation of Nu.450,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.

(2) Access and Benefit Sharing Agreement shall be liable for payment of fine of Nu.45,000.00 and compensation of Nu. 900,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.

(3) Material Transfer Agreement shall be liable for payment of fine of Nu. 5,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation; and

(4) Standard Material Transfer Agreement shall be liable for payment of fine of Nu.5,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.

134. In accordance with section 157 and 158 of the Act, any person who knowingly provides access to traditional knowledge associated with genetic resources except as permitted under customary practice shall be liable for payment of fine of Nu. 25000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.

Unauthorized transfer of research result or accessed genetic resources

135. In accordance with section 159 of the Act, any User who transfers research results or accessed genetic resources to a third-party for product development and commercial utilization in contravention to sections 81 and 82 of the Act and section 106 to 111 of this Rules except for academic research not intended for product development and commercial utilization shall be liable for payment of fine of Nu. 45,000.00 and compensation of Nu.900,000.00; or equivalent to US Dollar at the prevailing rate on the day of imposition of fines and compensation.

Non-deposit of sample and specimen of biological resource

136. Any person or agency who fails to deposit samples and specimens of genetic resources as required under sections 137, 138 and 139 of the Act and section 125 of this Rules shall be liable for payment of fine of Nu. 5,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.

137. The National Focal Point shall publish the report on the failure to deposit samples and specimens of genetic resources in the Access and Benefit Sharing Clearing House upon approval of the Competent National Authority.

Subsequent Offense

138. Any person committing subsequent offense under section 133 to 136 of this Rules shall be imposed with double the fine amount of the first offense.

139. In the event of failure to pay the fines and compensation, the National Focal Point shall bar the proponent or User from accessing any genetic resources and such non-compliance shall be reported to the Access and Benefit Sharing Clearing House upon approval of the Competent National Authority.

CHAPTER 12

MISCELLANEOUS

Forms

140. The National Focal Point shall amend the forms under this Rules to accommodate relevant information.

Amendment

141. The amendment of these Rules by way of addition, variation or revision may be affected by the Competent National Authority.

Authoritative text

142. In any instance of difference in meaning between Dzongkha and English texts of this Rules, Dzongkha text shall be regarded as the authoritative. .

Definition

143. In addition to the definitions set out in the Act and for the purpose of this Rules, the following terms shall have the meaning ascribed to them in this section, unless the context otherwise provides:

(1) "Act" shall mean the Biodiversity Act of Bhutan, 2022.

(2) "Bhutanese entity" shall mean any company or business organization registered in Bhutan.

(3) 'Check point' shall mean any designated agency to collect or receive or verify relevant information as appropriate for collection, utilization, trade and transit of genetic resources.

(4) "Community" shall mean any group of people residing together in one Chiwog or Gewog.

(5) "Essentially Derived Variety" shall mean a new variety developed using protected variety retaining the essential characteristics of the protected variety.

(6) "Farmer" shall mean any person who is actively engaged in farming or agricultural activities

(7) "Farmers' Variety" shall mean a variety which has been traditionally cultivated and evolved by the farmers in their fields.

(8) "Growing test" shall mean cultivation of candidate variety in the field or greenhouse comparing with similar existing varieties by evaluating morphological and physiological traits.

(9) "Invasive alien species" shall mean plants, animals, pathogens and other organisms that are non-native to an ecosystem, and which may cause economic or environmental harm or adversely affect human health. In particular, they impact adversely upon biodiversity, including decline or elimination of native species - through competition, predation, or transmission of pathogens - and the disruption of local ecosystems and ecosystem functions.

(10) “International entity” shall mean any foreign company or business organization based in foreign land.

(11) “Non-commercial” shall mean any activity without commercial intent.

(12) “New Variety” shall mean a variety developed by a breeder which conforms to the criteria for Novelty, Distinctiveness, Uniformity, Stability and Identifiability.

(13) “On-site inspection” shall mean the conduct of systematic inspection of the site where the seed variety is grown by the applicant or the relevant agency responsible for carrying out the testing in compliance to Novelty, Distinctiveness, Uniqueness, Stability and Identifiability criteria.

(14) “Person” shall mean any natural or legal person.

(15) “Rules” shall mean the Biodiversity Rules and Regulations of Bhutan, 2023.

(16) “Seed” shall mean any unit of reproduction used for sowing or planting and includes seed of food, feed, forages, fruits and vegetable crops. It also includes seedlings and tubers, bulbs, rhizomes, roots, cuttings, all types of grafts and other vegetatively propagated materials.

.

Form I: Application form for Registration of Plant Variety under the 'Sui Generis System of Protection of Plant Varieties'

[See section 32 of Biodiversity Rules and Regulations 2023]

Instruction to applicant: Wherever a box item appears against queries, please tick the relevant box and provide legibly written/typed response in other queries

Section 1: Identity of the Applicant(s):

- ☐ Individual Breeder(s)
- ☐ Successor of Breeder
- ☐ Farmer/Farming Community
- ☐ Institutional/Employer
- ☐ Assignee of Any of Above

Section 2: Name(s) of Applicant(s)

(If natural person): (Insert additional rows, if required)

Name(s):
Complete Address:
Dzongkhag:

If a legal person; for example, a firm or company or institution)

Name:
Complete Address:
Year of Registration:

Section 3: General Information of the Candidate Variety:

Common Name of the Crop:
Scientific Name:
Family:
Denomination (in block letters):

Section 4: Type of Variety (see section 29 of the Sui Generis System of Protection of Plant Varieties and of Biodiversity Act of Bhutan 2022)

- ☐ New Variety
- ☐ Farmers' Variety

**If new variety is a tGMO/GMO attach clearance on Biosafety from BAFRA.*

Section 5: Names and Addresses of Breeder(s) who has/have bred the Candidate Variety*:

Name:
Address:
Telephone:
Email:
Nationality:

**In case of more than one breeder, mention all names as (ii), (iii) and so on in the above format. If required insert an extra page.*

a. **What is (are) the Novelty, Distinctness, Uniformity, Stability and Identifiability feature on the basis of which registration is sought. Explain in detail the group characters.**

Has the candidate variety been commercialized or otherwise exploited?

Yes ☐ No ☐

*If yes, please indicate the following:

Date of the first sale of the variety:

Denomination used:

Variation in important trait with Respect to first filing: (attach sheet)

b. **If the candidate variety is a hybrid, state whether all the parental lines required for the repeated propagation of the hybrid are bred exclusively by the applicant(s):**

Yes ☐ No ☐

*If no, mention which of the parental line is outsourced, whether letter of agreement is obtained for each of the outsourced protected parental lines in compliance with Section 35 of the Sui Generis System for Protection of the Plant Varieties of the Biodiversity Act of Bhutan 2022 and also provide following information on each of them:

Parental line (S):

Denominations[7]:

Source:

Authorisation letter obtained: Attached ☐ Not attached ☐

**Denomination should not be altered from what was used at the source. Information on source may include name of breeder or institution or farmer or farming community who had bred and maintained the parental line. Repeat above information for additional applicable parental line.*

c. **State if any Farmers' Variety or Variety of Common Knowledge or variety in public domain is used as parental line for the repeated propagation of the hybrid:**

Yes ☐ ☐

*If yes, give following details:

Denomination:

Geographical Source:

Details of Attribution (origin):

Details of owner farmer /village community/ Institution/ Organisation:

d. **The Sui Generis System of Protection of Plant Varieties under the Biodiversity Act of Bhutan 2022 provides access to benefit sharing to farmers who have conserved the genetic resource that has contributed towards variety development. In this particular case what sort of farmer/community recognition the Applicant has planned?**

e. **In case exotic germplasm was used in the derivation of the variety or hybrid, give details:**

Section 6: Declarations

The undersigned hereby apply for the grant of registration of the candidate variety with the above said denomination and I/we am are conversant with the Sui Generis System of Protection of Plant Varieties and Rules thereof related to this application under the aegis of Biodiversity Act of Bhutan 2022.

The undersigned hereby declare that no person other than the person or persons mentioned in this application has been involved in the breeding, or discovery or development of the candidate variety.

The undersigned hereby declare that the candidate variety complies with the section 29 to 34 of Sui Generis System of Protection of Plant Varieties of the Biodiversity Act of Bhutan 2022.

The undersigned hereby declare that I/we have not applied for or received a trademark for the said denomination of the variety.

The undersigned hereby declare that the information given in this application for the registration of the above said candidate variety, including annexure and all supporting documents are complete, true and correct to the best of my/our knowledge, information and belief and no information has been willfully concealed.

The undersigned hereby declare that genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired.

The undersigned hereby declare that the undersigned shall abide by all the provisions and guidelines of Sui Generis System of Protection of Plant Varieties of the Biodiversity Act of Bhutan 2022.

Signature of Applicants

**Wherever the applicants are more than one person each applicant has to sign. In the case of authorized application or application by assignees, such person(s) authorized or assigned shall sign*

Annex I: Following are the attachments (duly signed/seal) to be submitted along with application:

- complete application;
- document of authorization;
- document of assignment;
- documents in support of (b) and (c) as given above. (If applicable);
- affidavit that the Terminator Technology and the Genetic Use Restriction Technology is not involved;

- technical Questionnaire for the Candidate variety (attached);
- in case of transgenic relevant Genetic Engineering Approval Committee clearances and approvals; and
- Fees as applicable;

***If felt necessary attach colour pictures of specific characteristics used for establishing distinctness. Please sign each page of the application and other documents on the left margin.*

Form II: Assignment of Application or Restitution of the Title

Application form for the assignment of application or restitution of the Title of variety rights under section 38 and 39 of the Act

This application is with regard to the plant variety protection number…… of the ……. variety of …….crop registered in the name of ……..

The undersigned would like to submit that the grant of plant variety protection to the aforementioned variety may be reassigned/restituted based on the following.

(a) The information provided by the applicant is incorrect.

(b) The plant variety protection is granted to a person who is not eligible for protection under the Act.

(c) The rightful owner of the Title of the variety rights is as follows:

- Name:
- Address:
- Telephone:
- Email:
- Nationality:

(d) Proof of breeding is submitted

Form III: Access proposal

Form for Access Proposal *(Information included in this Form shall be in sufficient detail to enable the relevant authorities to make a decision whether to grant or refuse Access)*

Section 1. Applicant

Name: _____
Address: _____
Works Tel _____ Home Tel _____
E-mail address: _____
Mobile: _____
Name and address of principal researcher:
Address of the contact person/agent if any in Bhutan: _____

Section 2. Category

(*Tick the relevant box*)

Type of Phase

□ Scoping □ Access and Benefit Sharing

Type of Resources

□Genetic Resources □ Associated Traditional Knowledge □ others (specify)

Section 3. Application Checklist

The following list outlines all of the information necessary to provide a timely decision on your application. All items on the list must be provided with the application. We are unable to accept applications that do not have all of the required items.

□ Profile of the organization including Board of Directors and Shareholders.
□ Company's Article of Incorporation.
□ Copy of passport of foreign applicant (if investor is individual).
□ Power of Attorney for the authorized representative or contact person.
□ Identity and responsibilities of all entities who will be involved in the activities, if any.
□ Annual turnover of the organization in Ngultrum or US dollars (including Tax return or audited accounts of foreign investors for the last 3 years).
□ Equipment and laboratories relevant to the activity.

Section 4: Proposal

The proposal shall include:

a) Identification (scientific name) of genetic resource and its use, description and nature of traditional knowledge (oral/documented).
b) Purpose for which access is requested including the type and extent of research, mechanism for sharing of results, commercial use being derived and expected to be derived from it and any other benefits anticipated.
c) Geographical location of proposed collection.
d) Any identified individual or community for access to traditional knowledge.
e) Quantity of biological resources to be collected.
f) Information of collaborating local partners.
g) Information on the arrangements made within Bhutan to facilitate the collection.

h) Whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access.
i) Nature of legal rights including any intellectual property rights the applicant intends to seek over the accessed genetic resources and ensuing innovations.
j) Work plan and timeframe within which the project is to be completed.

Section 5. Others

1. Information on the primary destination of the resources and any expected subsequent destinations of the resources.
2. Potential economic and other benefits including those resulting from any Intellectual Property Rights (IPR) and patent obtained out of accessed biological resources and knowledge that are intended, or may accrue to the applicant or to the country he/she belongs.

Section 6. Declaration

The undersigned, being duly authorized, declare to the best of my knowledge and belief that the information contained in this application is correct and complete and I authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application.

In case, the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed: _____
Date: _____
Name:_____
In the capacity of: _____

Form IV: Prior Informed Consent

Form for Prior Informed Consent

Section 1. *Details of the Provider of Genetic Resources or holder of associated Traditional Knowledge*

Name: _____
Dzongkhag:_____
Gewog:_____
Village_____
Works Tel _____ Home Tel _____
E-mail address: _____
Mobile: _____

Section 2. *Category*
(*Tick the relevant information*)
Phase
□ Scoping □ Access and Benefit Sharing □ others (specify)

Type of Resources
□ Genetic Resources □ Associated Traditional Knowledge

Section 3: *Details of the Genetic Resources or Tradition Knowledge*

1. Scientific description of genetic resources to be collected or associated traditional knowledge:
2. Purpose for which access is requested:
3. Location where activities will take place:
4. Proposed starting & ending date:…….. (month/day/year)
5. Describe the economic, social, technical, scientific, environmental and other benefits that this activity may likely accrue to Bhutan and other relevant stakeholders:

Section 4: *Consent*

Do you agree to the following?	Yes	No
Use of genetic resources or traditional knowledge by …… for research on new compound and product development.		
Sharing of genetic resources or traditional knowledge with others.		
Others (specify)		

I/we have voluntarily decided to select the option or options which I/we have ticked above.

Name of Provider
Date

Signature of National Focal Point

Form V: Scoping Agreement

Reference No_____ Date ___, ___, ___

SCOPING AGREEMENT

This Agreement is made between:

Ministry of Agriculture and Livestock, Royal Government of Bhutan acting through and represented by the **Program Director, National Biodiversity Centre** being the authorized officer of the National Focal Point having its office at Serbithang, Thimphu, Bhutan (hereinafter referred to as "the NFP")

And

User, established and existing under the laws …… with a capital of…… having its registered office at …… (hereinafter referred to as User)

Article 1 – Preamble

1.1 The NFP has been established by the Royal Government of Bhutan (hereinafter referred to as RGoB) under the powers granted to it by Section 16 of the Biodiversity Act of Bhutan 2022 under which, the NFP is the entity vested with the responsibility to regulate the access to genetic resources and benefit sharing in the country and authorized to permit access to any genetic resources and /or associated traditional knowledge found within the territory of Bhutan upon the approval of the Competent National Authority (CNA) established under Section 13 of the Biodiversity Act of Bhutan 2022 (hereafter referred to as the Act).

1.2 The NFP through this agreement furnishes the Prior Informed Consent (PIC) from providers of genetic resources and/or associated traditional knowledge for granting the access.

1.3 The **User** acknowledges that the RGoB retains legal ownership of Bhutan's genetic resources and /or associated traditional knowledge and the associated intellectual property rights unless determined under this Agreement.

1.4 This Agreement is for granting approval for the scoping phase of access to Bhutan's genetic resources and /or associated traditional knowledge specified under Section 4 of this Agreement.

1.5 **User** seeks to engage in the scoping phase of the utilization of Bhutan's genetic resources and /or associated traditional knowledge and has made an application to the NFP for approval.

1.6 Access to Bhutan's genetic resources shall be divided in two phases: *a Scoping Phase* and *an Actualization Phase* with differing conditions for each phase.

1.7 The Scoping Phase to conduct exploratory research will require a Scoping Permit which shall be in the form of a Scoping Agreement and contain a set of conditions for utilization of such resources.

1.8 Based on the outcome of the Scoping Phase if **User** intends to undertake any step to commercialize or engage in focused research on such resources and/or research results which may include but is not limited to applications for intellectual property rights, product development and testing and marketing; **User** shall enter into an Access and Benefit Sharing (ABS) Agreement and secure Actualization Permit prior to engaging in such steps or the Actualization Phase of utilization of such resources.

1.9 Benefit sharing under the ABS Agreement during Actualization Phase shall be based on each party's contribution, fairness and mutual consensus.

1.10 The NFP and **User** shall jointly be referred to as "Parties" and now therefore, the "Parties" hereto hereby agree as follows:

Article 2– Definitions

2.1 In this Agreement, unless the context otherwise requires, the expression set out below shall have the following meaning:

Genetic Resources means all material of plant, animal, microbial or other origin containing functional units of heredity and include the biochemical composition of genetic resources, genetic information and derivatives.

Traditional Knowledge associated with genetic resources means the knowledge, innovations and practices of Bhutanese communities that is related to the utilization of biodiversity and is not limited to knowledge relating to genetic structure of biological resources.

Access to Genetic Resources means the utilization of genetic resources from Bhutan irrespective of whether they are accessed *in situ* or *ex situ* for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology. Access to genetic resources also includes the conducting of any research and development on derivatives of biological or genetic resources from Bhutan.

Access to Traditional Knowledge associated with genetic resources means the utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and development.

Bhutan Access and Benefit Sharing Fund (BABS Fund) means a fund established under **section 128 of the Act** to receive monetary benefits derived from the research and

commercial utilization of Bhutan's genetic resources and/or associated traditional knowledge including processing fee and commitment fee payable at the Scoping phase.

Act means the Biodiversity Act of Bhutan 2022 and includes any subsequent amendment or re- enactment of the Act

Rules means the Biodiversity Rules and Regulations 2023

Policy means the Interim Access and Benefit Sharing Policy of Bhutan 2015.

The scoping phase of utilization of genetic resources and/or associated traditional knowledge means the initial exploratory phase of research and development with the aim of establishing market or research potential.

The actualization phase of utilization of genetic resources and/or associated traditional knowledge means the phase when specific steps are undertaken to commercialize or engage in focused research on such resources and/or knowledge. The actualization phase includes, but is not limited to applications for intellectual property rights, product development and testing and marketing.

Third Party means any person or institution other than the National Focal Point, the User or any collaborator under their control or supervision.

User means a person (individual or organization) named as the User and includes their authorized representative, where the context permits.

Article 3– Grant of Access

3.1 The NFP hereby grants approval for access to genetic resources and/or associated traditional knowledge listed under annex-1 for the scoping phase for the purpose of……. subject to the terms and conditions set forth in this Agreement.

3.2 Any activity/usage involving the genetic resources and/or associated traditional knowledge that is not expressly authorized by the provisions of this Agreement and any additional annexure (s) hereto is deemed as prohibited.

3.3 **User** hereby agrees that, this Agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Parties hereto or make them in any way liable as partners of or as agents for one another. No Party has the authority to act for or to assume any obligation or responsibility on behalf of the other Party and the relationship between the Parties is that of a legal or natural person and a statutory authority competent to approve access to genetic resources under the Act.

Article 4– Conditions for Access

4.1 **User** shall have access only to the genetic resources and/or associated traditional knowledge approved by the CNA and listed under Annex-1 of this agreement and only for the purpose approved under this Agreement.

4.2 **User** shall pay such sum of US dollar 500.00 (US dollar five hundred only) as a processing fee for the Scoping Permit/Agreement and sum of US dollar 5000.00 (US dollar five thousand only) as a commitment fee as specified **section 80** of the Act. The processing fee and the commitment fee shall be deposited in Bhutan ABS Fund dedicated to support conservation and sustainable use of Bhutan's biodiversity and associated traditional knowledge, and enhancement of rural livelihoods as specified in **section 130** of the Act.

4.3 **User** undertakes to abide with the provisions of the Act and other related legislations in force in Bhutan and as amended in the future.

4.4 **User** undertakes to facilitate measures for the conservation and sustainable use of genetic resources and to minimize any negative environmental or social impact of the collecting the genetic resources and other research activities.

4.5 **User** shall not distribute, transfer or part with the accessed genetic resources and associated information to any third party without prior written approval of CNA nor engage in the 'actualization phase' of the accessed resources under this Agreement and signing of appropriate Agreement and issuance of Actualization Permit.

4.6 **User** undertake to submit a status report in English on yearly basis on the progress of the scoping phase to the NFP for submission to the CNA by 31st of December.

4.7 The CNA reserves its right to supervise the access process to the genetic resources and/or associated traditional knowledge, and the research as it may deem fit.

4.8 Any violation of above conditions will be deemed to be material breach of this Agreement making the Agreement voidable at the option of the NFP.

Article 5– Third Party Transfer and Assignment

5.1 Without the prior written approval of the CNA through NFP in each instance, neither this Agreement nor the approval granted hereunder shall be transferred or assigned in whole or in part by **User** to any natural or legal person whether voluntarily or involuntarily, by operation of act or omission on the part of User or otherwise.

5.2 In the event of any substantial changes in the management or shareholding of **User,** that alters the control structure of **User** and includes changes brought by a transfer of business units, merger, demerger or any other kind of corporate restructuring, **User** shall ensure that the obligations under this agreement perpetuate and provide written notice to the NFP not less than **ninety (90)** days prior to initiating such changes.

Article 6– Other Conditions

6.1 **User** shall submit in English a hard and soft copy of its scoping findings in the form of reports, publications, thesis or any other documents to the NFP as soon as the scoping is completed or published or expiry of the term of the Agreement whichever is earlier. The NFP on behalf of the RGoB shall have full ownership of the results of the scoping phase if User decides not to enter into an 'actualization

phase' of the utilization of Bhutan's genetic resources and/or associated traditional knowledge.

Article 7– Liabilities and Indemnification

7.1 **User** shall be solely responsible for any claims by third parties arising from the **User's** acts or omissions in the course of performing this Agreement and under no circumstances shall the NFP be held responsible or liable for any claims by such third parties.

7.2 **User** shall indemnify and protect the NFP and its employees from and against all claims, demands, losses, damages, costs (including attorney fees), actions, suits or other proceedings, all in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of **User,** its employees or agents, (whether by reason of negligence or otherwise) in the performance by or on behalf of **User** of the provisions of this Agreement or any activity undertaken or purported to be undertaken under **User's** authority or pursuant to the terms of this Agreement.

7.3 **User** undertakes to pay such a sum as determined by NFP and mutually agreed for any breach of this agreement and loss incurred in Bhutan.

Article 8– Term of the Agreement and Termination

8.1 This Agreement, unless terminated as provided herein, shall remain in effect for a period of ……from the date of signing of this Agreement by the Parties. However, the obligations of **User** with respect to the utilization of Bhutan's genetic resources and/or associated information under this Agreement will remain in perpetuity.

8.2 The NFP upon approval of CNA may terminate the rights under this Agreement and revoke the Scoping Permit by a written notice if **User** defaults in the performance of any obligations under this Agreement and the default has not been remedied within ninety (90) days after the date of notice in writing of such default by NFP.

8.3 **User** agrees to forfeit its deposit in situations where the NFP terminates this Agreement and revokes the Scoping Permit under the conditions listed in 8.2 of this Agreement.

8.4 **User** may terminate this Agreement by giving ninety (90) days advance written notice stating valid reasons for the same. However, such termination shall come into effect only on acceptance of the same by the NFP given in writing not later than thirty (30) days after the notice period and payment of all outstanding dues and submission of mandatory reports on scoping conducted until then by **User**.

8.5 **User** agrees to transfer to the NFP all the data/results/conclusions of the scoping phase in the instance of the termination of this Agreement.

8.6 **User** agrees to return the genetic resources remaining and/or associated information to NFP no later than thirty (30) days after the termination of this Agreement. The costs incurred in transferring these resources back to the NFP will be borne by **User**.

8.7 The NFP shall not be liable for any loss or damage whatsoever caused to **User** due to revocation of approval for access and/ or termination of this Agreement on any ground whatsoever.

8.8 **User** on termination of the Agreement, agrees not use any of the data/results/conclusions from the research on the accessed material for any purpose whatsoever without the prior approval of the NFP.

Article 9– Notice

9.1 Wherever in this Agreement, it is required or permitted that any communication, notice or demand be given or served by either Party to or on the other Party, such communication, notice or demand will be in English and in writing and will be validly given or sufficiently communicated if forwarded by registered post with acknowledgement due, e-mail, telegram, telex or facsimile as follows:

The addresses of the Parties for communication:

NFP	**User**
Program Director National Biodiversity Centre Ministry of Agriculture and Livestock P.O. Box 875, Serbithang Thimphu, Bhutan	

9.2 Notice will be deemed to have been delivered:

a. If delivered by hand/courier, upon receipt;

b. If sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation weekends and public holidays;

c. If sent by certified post, four (4) days after the mailing thereof, provided that if there is a postal strike or other disruption such notice will be delivered by hand or electronic transmission.

9.3 The Parties may change their respective addresses for delivery by delivering notice of change no later than thirty (30) days after such change has been undertaken.

Article 10– Confidentiality

10.1 Upon request from User, NFP agrees to keep the research being carried out and the progress achieved as ***confidential***. However, confidential information may be disclosed to the extent required by any law or regulation or order of any governmental/administrative/judicial authority having jurisdiction over any of the Parties.

10.2 This confidentiality clause does not apply in cases where the NFP terminates this Agreement and revokes the Scoping Permit under Section 8.2.

Article 11– Interpretation

11.1 Any interpretation of words or phrases of this Agreement shall be in accordance with the purpose, spirit and letter of the Act and as defined in this Agreement.

Article 12– Arbitration

12.1 If any difference in interpretation or dispute (hereinafter referred to as a 'Dispute') between the Parties arises under this Agreement, any Party may give the other Party a written notice clearly identifying and providing details of the Dispute. On receipt of such notice by the other Party, the Parties shall try to settle the Dispute amicably between them by negotiating in good faith within thirty (30) days of the receipt of such notice.

12.2 If the Dispute is not resolved by such negotiations within the period mentioned, the Parties agree to settle the Dispute through arbitration conducted by the sole arbitrator appointed by the NFP. The place of arbitration shall be in Thimphu, Bhutan. The language to be used in the arbitration proceedings shall be normally in English.

12.3 The Parties agree that the award and determination of the arbitrator shall be final and binding on the Parties.

Article 13– Governing Law and Jurisdiction

13.1 This Agreement is governed by and is to be construed in accordance with the laws of Bhutan without regard to the principles of conflict of laws. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the courts in Bhutan.

Article 14– Severability

14.1 If any part of this Agreement is declared or held invalid by a court of law for any reason, the invalidity of that part will not affect the validity of the remainder which will continue in full force and effect and be construed as if the Agreement had been executed without the invalid portion.

Article 15– Modification

15.1 No amendment or modification to this Agreement shall be valid or binding upon the Parties, unless agreed upon by the Parties, made in writing, and signed on behalf of each Party by their duly and legally authorized signatories and made as annexure to this Agreement.

Article 16– Entirety of Agreement

16.1 This Agreement constitutes the culmination of all prior negotiations, understandings, representations and commitments and sets down the complete terms and conditions of Agreement between the parties as to the subject matter.

Article 17– Representations

17.1. The Parties represent to each other that they have the legal right and power to enter into this Agreement and to perform its obligations under the terms of this Agreement and its execution, delivery and performance by and has been duly and validly authorized by all necessary corporate action or Government action on its part.

17.2. The signatories to this Agreement shall be duly authorized by the Parties and certified copies of such authorization are appended as Annexure (s).

This Agreement has been executed in duplicate, each of which shall be deemed to be original; one shall be retained by the NFP and other by **User** and both shall constitute one and the same instrument.

Article 18 – Signature and Acceptance

In witness thereof, the parties have executed this Agreement on the dates set forth below.

Seal & Dated Signature [_____] Seal & Dated Signature [_____]

For the NFP **Witness**

Name: Name:

Designation: Designation:

Nationality ID Number: Nationality ID Number:

Mailing Address: Mailing Address:

For the User **Witness**

Seal & Dated Signature [_____] Seal & Dated Signature [_____]

Name: Name:

Designation: Designation:

Nationality ID Number: Nationality ID Number:

Mailing Address: Mailing Address:

Annex-1

Sl. No	Botanical Name	Common Name	Local Name	Family

Form VI: Form for seeking approval for third party transfers of the accessed genetic resources and/or associated Traditional Knowledge.

Form for seeking approval for third party transfers of the accessed genetic resources and/or associated Traditional Knowledge.

Section 1. Details of the Third Party

Name: _____

Address: _____

Works Tel _____ Home Tel _____

E-mail address: _____

Mobile: _____

Name and address of principal researcher: _____

Section 2. Details of the First Party

Name: _____

Address: _____

Works Tel _____ Home Tel _____

E-mail address: _____

Mobile: _____

Section 3. Third Party Checklist

The following list outlines all of the information necessary to provide a timely decision on your application. All items on the list must be provided with the application. We are unable to accept applications that do not have all of the required items.

- □ Profile of the organization including Board of Directors and Shareholders.
- □ Company's Article of Incorporation.
- □ Copy of passport of foreign applicant (if investor is individual).
- □ Power of Attorney for the authorized representative or contact person.
- □ Identity and responsibilities of all entities who will be involved in the activities, if any.
- □ Annual turnover of the organization in Ngultrum or US dollars (including Tax return or audited accounts of foreign investors for the last 3 years).
- □ Equipment and laboratories relevant to the activity.

Section 4: Application Details

The application shall include:

a) Identification (scientific name) of genetic resource and its use, description and nature of traditional knowledge (oral/documented).
b) Purpose of the intended third party transfer including the type and extent of research.
c) Details of the contract entered with the first party (Copy to be enclosed).
d) Details of the benefits and mechanism/arrangements for benefit sharing already implemented, if any.
e) Estimation of benefits that would flow to Bhutan arising out of the third-party transfer of accessed biological resources/associated traditional knowledge.
f) Proposed mechanism and arrangements for benefit sharing arising out of the proposed third-party transfer.
g) Nature of legal rights including any intellectual property rights the third party intends to seek over the accessed genetic resources and ensuing innovations.

h) Information on the primary destination of the resources and any expected subsequent destinations of the resources.
i)
j) Work plan and timeframe within which the project is to be completed.

Section 5. Declaration

The undersigned, being duly authorized, declare to the best of my knowledge and belief that the information contained in this application is correct and complete and I authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application.

In case, the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed: _____
Date: _____
Name:_____
In the capacity of: _____

Form VII: Access and Benefit Sharing Agreement

Reference No_____ Date ___, ___, ___

This Agreement is made between:

User, a business entity holding trade licence no……., with its registered office at Thori Lam, Changangkha Thimphu Bhutan[hereinafter referred to as the "**User**"]; and

Provider, ……. [hereinafter referred to as the "**Provider**"]; in presence of

Ministry of Agriculture and Livestock, Royal Government of Bhutan acting through and represented by the **Program Director, National Biodiversity Centre** being the authorised officer of the National Focal Point having its office at Serbithang, Thimphu, Bhutan (hereinafter referred to as "the NFP")

Article 1 – Preamble

1.1 The NFP has been established by the Royal Government of Bhutan (hereinafter referred to as RGoB) under the powers granted to it by Section 16 of the Biodiversity Act of Bhutan 2022 under which, the NFP is the entity vested with the responsibility to regulate the access to genetic resources and benefit sharing in the country and authorized to permit access to any genetic resources and /or associated traditional knowledge found within the territory of Bhutan upon the approval of the Competent National Authority (CNA) established under Section 13 of the Biodiversity Act of Bhutan 2022 (hereafter referred to as the Act).

1.2 The Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) to which Bhutan is a party gives the responsibility to manage biological diversity to ensure fair and equitable sharing of the benefits arising from the use of genetic resources.

1.3 Realizing the benefits that the country may accrue from regulating access to its genetic resources and ensuring fair and equitable sharing of benefits, the Biodiversity Act of Bhutan 2022 was enacted to provide for detailed provisions relating to access to genetic resources and benefit sharing.

1.4 The **User** intends to access genetic resources specified in this Agreement from the Kingdom of Bhutan.

1.5 The NFP through this agreement furnishes the Prior Informed Consent (PIC) from providers of genetic resources and/or associated traditional knowledge for granting the access.

1.6 The **User** acknowledges that the RGoB retains legal ownership of Bhutan's genetic resources and /or associated traditional knowledge and the associated intellectual property rights unless specified under this Agreement.

1.7 In consideration of the grant of access to genetic resources and/or associated traditional knowledge, the User is entitled to access and use the genetic resources and/or associated traditional knowledge in accordance with this Agreement and shall agree to share the benefits specified herein.

1.8 The **Provider** and **User** shall jointly be referred to as "Parties" and now therefore, the "Parties" hereto hereby agree as follows:

Article 2– Definitions

2.1 In this Agreement, unless the context otherwise requires, the expression set out below shall have the following meaning:

Access Area means the area from which the User will have access to biological resources.

Genetic Resources means all material of plant, animal, microbial or other origin containing functional units of heredity and include the biochemical composition of genetic resources, genetic information and derivatives.

Access to Genetic Resources means the utilization of genetic resources from Bhutan irrespective of whether they are accessed *in situ* or *ex situ* for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology. Access to genetic resources also includes the conducting of any research and development on derivatives of biological or genetic resources from Bhutan.

Traditional Knowledge associated with genetic resources means the knowledge, innovations and practices of Bhutanese communities that is related to the utilization of biodiversity and is not limited to knowledge relating to genetic structure of biological resources.

Access to Traditional Knowledge associated with genetic resources means the utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and development.

Bhutan Access and Benefit Sharing Fund (BABS Fund) means a fund established under **section 128 of the Act** to receive monetary benefits derived from the research and commercial utilization of Bhutan's genetic resources and/or associated traditional knowledge including processing fee and commitment fee payable at the Scoping phase.

Act means the Biodiversity Act of Bhutan 2022 and includes any subsequent amendment or re-enactment of the Act

Rules means the Biodiversity Rules and Regulations 2023

Policy means the Interim Access and Benefit Sharing Policy of Bhutan 2015.

Commercial utilization means applying for, obtaining or transferring intellectual property rights by sale or license or in any other manner, or commencement of product development, conducting market research or the sale of any resulting product.

Product means material produced, obtained, extracted or derived through research and development activity.

Prior Informed Consent means a process through which the National Focal Point seeks the consent of the providers of genetic resources or holders of associated traditional knowledge.

Provider means a person (individual or organization) named as Provider and includes their authorized representative, where the context permits.

Third Party means any person or institution other than the Provider, the User or any collaborator under their control or supervision.

User means a person (individual or organization) named as the User and includes their authorized representative, where the context permits.

Article 3– Interpretation

3.1 Clause heading are inserted for convenient reference only and have no effect in limiting or extending the language of provisions to which they refer.

3.2 Words importing a person include a partnership and a body whether corporate or otherwise.

3.3 A reference to any legislation includes any statutory modification, substitution or re-enactment of such legislation.

3.4 The schedules form an integral part of this Agreement.

Article 4– Prior Informed Consent

4.1 This Agreement is made pursuant to the Prior Informed Consent (PIC) given by the Provider granting the access to genetic resources and/or traditional knowledge associated with genetic resources as specified in **section 66** of the Act

Article 5– Grant of Access

5.1 The **User** shall have access to the genetic resources and/ or traditional knowledge associated with genetic resources as specified in Schedule A of this Agreement.

5.2 The **User** shall pay such sum of US dollar 500 (US dollar five hundred only) as a processing fee for the ABS Agreement and sum of US dollar 5000 (US dollar five thousand only) as a commitment fee as specified **section 80** of the Act. The processing fee and the commitment fee shall be deposited in Bhutan ABS Fund dedicated to support conservation and sustainable use of Bhutan's biodiversity and associated traditional knowledge, and enhancement of rural livelihoods as specified in **section 130** of the Act.

Article 6– Conditions for Access

6.1 The **User shall** have access only to the genetic resource specified in Schedule A of this Agreement and undertakes to access the same in accordance with the conditions specified in this Agreement.

6.2 The **User** shall attach details of the commercial utilization of the genetic resources and/or associated traditional knowledge accessed in accordance with Schedule B of this Agreement.

6.3 Any use involving the genetic resource and/or associated traditional knowledge that is not expressly authorized by the provisions of this agreement shall be deemed to be expressly prohibited.

6.4 The **User** undertakes that it shall not allow any persons other than its authorized employees under its direct control and supervision to have access to the genetic resource and/or associated traditional knowledge.

6.5 The **User** shall not obtain, transfer, and distribute any form of intellectual property rights associated with the genetic resource accessed under this agreement in any manner without obtaining the prior written approval of the CNA through NFP.

6.6 The **User** undertakes to comply with the existing national laws, regulatory mechanisms and international agreements or treaties for the access to genetic resources. Provided that in case of conflict between the national laws and international agreement, the national laws shall prevail.

6.7 **User** undertakes to abide by the provisions of the Act and other related legislations in force in Bhutan and as amended in the future.

6.8 The approval given under this agreement is without prejudice to any other permits or approval that may be required for the purpose of access to the genetic resources and/or associated traditional knowledge from any other authorities under any other laws in force in the territory of Bhutan.

6.9 The failure to acquire such permit or approval under clause 6.8 shall be deemed as a material breach of this agreement and shall result in the termination of this agreement. However, upon an application by the **User**, the **User** may be given the opportunity to rectify the default and obtain the required permit or approval within such time as may be granted by the CNA through NFP.

Article 7– Third Party Transfer

7.1 The **User** shall not transfer the results of research relating to any genetic resources and or associated traditional knowledge that is the subject of this Agreement to a third party without obtaining the approval of the CNA through NFP.

7.2 Without the prior written approval of CNA through NFP, neither this agreement nor the approval granted hereunder shall be transferred or assigned in whole or in part by the **User** to a third party.

7.3 In the event of any substantial changes in the management or shareholding of the **User** that alters the organizational or control structure of the **User** and includes changes brought by acquisition, merger, demerger or any other kind of corporate restructuring, the **User** shall ensure that the obligations under this agreement perpetuate and provide written notice to the NFP not less than ninety (90) days prior to initiating such changes.

Article 8– Liabilities and Indemnification

8.1 A relevant Party shall be solely responsible for any claims by third parties arising from its acts or omissions in the course of performing this agreement and under no circumstances shall the other relevant Party be held responsible or liable for any such claims by third parties.

8.2 A relevant Party shall indemnify the other relevant Party and its employees from and against all claims, losses, damages, costs (including attorney fees), actions, suits or other proceedings, in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of the relevant Party, its employees or agents, (whether by reason of negligence or otherwise) in the performance by or on behalf of the relevant Party of the provisions of this agreement or any activity undertaken or purported to be undertaken pursuant to the terms of this agreement.

Article 9– Benefit Sharing

9.1 The **User** shall pay to the Provider 15 % of annual gross ex-factory sales of the product on such date as may be agreed between the relevant parties.

9.2 Two (2) % of the total monetary benefits specified in clause 9.1 shall be paid to the BABS Fund.

9.3 The **User** shall adopt sustainable management of genetic resources while sourcing the genetic resources.

9.4 The **User** shall pay a premium price at a mutually agreed rate and quantity which shall be stipulated in a separate supply agreement executed between the User and the Provider under the guidance of NFP.

9.5 The User shall provide details of other benefits in the **Schedule C**

Article 10– Obligation of the Provider

10.1 The Provider has the obligation to facilitate access to the genetic resources and/or associated traditional knowledge which includes the facilitation in acquisition of permits required in accordance with the relevant national laws.

Article 11– Termination

11.1 This agreement, unless terminated as provided herein, shall remain in effect for a period of …….. years from the date of signing this agreement. In case the User continues the commercial utilization of the genetic resource mentioned in the agreement beyond the period initially agreed upon, the User shall apply for renewal to the NFP for subsequent required period at which time a new agreement has to be affected with relevant provisions agreed mutually.

11.2 The relevant Parties may terminate this agreement at any time by mutual agreement in writing by giving ninety (90) days advance written notice of termination. or either relevant Party may terminate this agreement by a written notice on the happening of any of the following:

a. if the User does not make a payment due and fails to clear such non-payment within thirty (30) days after the date of notice in writing of such non-payment; or

b. if the User becomes insolvent or has a petition in bankruptcy, winding up filed for or against it, such termination shall be effective immediately upon the NFP giving written notice to the User.

11.3 The NFP may upon seeking approval of CNA revoke access or approval granted to the applicant, if any of the following circumstances arise:

a. on the basis of reasonable belief that the person accessing the said genetic resource has violated any of the provisions of the Act or the condition on which approval was granted;

b. when the person has failed to comply with the terms of the agreement;

c. on failure to comply with any of the use conditions; or

d. on account of overriding public interest with reference to protection of environment and conservation of biological diversity and protection of the rights, livelihoods and knowledge of communities.

In the event of revocation of access or approval as mentioned above, this agreement shall automatically stand terminated.

11.4 Upon termination of this agreement, the User shall cease all use of the genetic resource and shall, upon request, return or destroy (at the option of the NFP) all genetic resources under its control or in its possession. The costs in this regard shall be borne by the User.

11.5 The NFP shall not be liable for any loss or damage whatsoever caused to the User due to revocation of approval for access and/ or termination of this agreement as provided in section 11.3 of this agreement.

11.6 The User upon termination of the Agreement, agrees not to use any of the data, results, or conclusions from the research on the accessed material for any purpose whatsoever without the prior approval of the CNA.

Article 12– Reports and Audit

12.1 The User shall submit to the National Focal Point yearly reports on the following:

a. the quantity of genetic resource accessed;
b. the total quantity of the products produced by the use of the accessed genetic resources and associated traditional knowledge;
c. audited financial statements; and
d. any other related information sought by the NFP by a written notice.

12.2 The User shall keep accurate records (together with supporting documentation) appropriate to determine all amounts due to the Provider. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate.

12.3 In conducting audits pursuant to section 12.1 and 12.2, such person shall have access to all records which he reasonably believes to be relevant to the calculation of monetary benefit.

Article 13– Confidentiality

13.1 The Provider and the NFP agrees to treat as confidential all confidential information marked as "CONFIDENTIAL" by the User and agrees that information disclosed in pursuance of this agreement relating to the formulations, including efforts to commercialize the formulations, shall be deemed confidential information.

13.2 The Provider and the NFP shall, upon due review of the need for confidentiality, maintain the confidentiality of information pertaining to the User at the written request of the User.

13.3 Notwithstanding clause 13.1 and 13.2, confidential information may be disclosed to the extent required by any law or regulation or order of any governmental, administrative, or judicial authority having jurisdiction over any of the Parties.

Article 14– Notice

14.1 Wherever in this agreement, it is required or permitted that a communication, notice or demand be given or served on any party, such communication, notice or demand will be given in writing and in English and will be validly given or sufficiently communicated if forwarded by Registered post or e-mail:

For the NFP:
Program Director
National Biodiversity Centre
Ministry of Agriculture and Livestock
Serbithang Thimphu
Tel # 02-351417/351218 Fax # 02-351219
Post Box No. 875

For the Provider:

For the User:

14.2 Notice will be deemed to have been delivered:

i. if delivered by hand, upon receipt;

ii. if sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation of weekends and public holidays; or

iii. if sent by post, seven (7) days after the mailing thereof.

14.3 The Parties may change their respective addresses for delivery by delivering notice of change as provided in this paragraph.

Article 15– Governing Law and Jurisdiction

15.1 This agreement is governed by and is to be construed in accordance with the laws of Bhutan.

Article 16– Arbitration

16.1 Subject to clause 15.1 any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination shall try to settle the dispute amicably between them by negotiating in good faith.

16.2 If the dispute is not resolved under clause 16.1, the Parties agree to settle the dispute through arbitration. The arbitration shall be governed by the Alternate Dispute Resolution Act of Bhutan, 2013. The place of arbitration shall be in Thimphu, Bhutan. The language to be used in the arbitration proceedings shall be in English.

Article 17– Severability

17.1 If at any time, any provision of this Agreement is or becomes illegal, invalid or unenforceable, either the legality, validity or enforceability of the remaining provisions will in any way be affected or impaired.

Article 18– Severability

18.1 No amendment or modification of this agreement shall be valid or binding upon the parties, unless agreed upon by both parties, made in writing, and signed on behalf of each of the Parties by their authorized representatives.

Article 19– Benefit of Agreement

19.1 This Agreement shall bind and inure to the benefit of the successors and assignees of the parties. However, none of the relevant Parties may assign or delegate any of its rights or obligations herein without the prior written consent of other relevant party and the NFP.

Article 20– Representations

20.1 Either relevant Party represents to each other Relevant Party that it has the legal right and power to enter into this agreement or to perform its obligations under the terms of this agreement and the execution, delivery and performance of this agreement by it has been duly and validly authorized by all necessary action on its part.

Article 21– Miscellaneous

21.1 The User hereby agrees that this agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Relevant Parties hereto or make them in any way liable as partners of or as agents for one another.

21.2 The documents attached hereto as Schedules form an integral part of this agreement, and consists of:

Schedule A: Access to Genetic Resources

Schedule B: Details of Commercial Utilization of genetic resources

Schedule C: Details of Benefit Sharing mutually agreed and delivery mechanism

21.3 Payments to be made under this Agreement shall be channeled through banking instruments accepting payment in cash.

This Agreement has been executed in duplicate, each of which shall be deemed to be original; one shall be retained by the NFP and other by **User** and both shall constitute one and the same instrument.

Article 18 – Signature and Acceptance

In witness thereof, the parties have executed this Agreement on the dates set forth below.

Seal & Dated Signature [_____] Seal & Dated Signature [_____]

For the Provider **Witness**

Name: Name:

Designation: Designation:

Nationality ID Number: Nationality ID Number:

Mailing Address: Mailing Address:

For the User **Witness**

Seal & Dated Signature [_____] Seal & Dated Signature [_____]

Name: Name:

Designation: Designation:

Nationality ID Number: Nationality ID Number:

Mailing Address: Mailing Address:

For the NFP **Witness**

Seal & Dated Signature [_____] Seal & Dated Signature [_____]

Name: Name:

Designation:	Designation:
Nationality ID Number:	Nationality ID Number:
Mailing Address:	Mailing Address:

Schedule A: Access to genetic resources

Sample of biological resources to be collected: [include name of species or lowest level of taxon, to which the resources belong; mention form of biological resource to be collected (leaves, stem, flower, roots etc.]
Access Area: [state the area from which the sample will be taken]
Time and Frequency of entry to access area: [state the anticipated dates and times of entry to access area]

Purpose of Access: [provide a brief description of the purpose(s) of collecting samples including end products.]
Labelling of Samples: [include a statement setting out the means of labelling the samples]

Schedule B: Details of commercial utilization of genetic resources

(Please provide detail the detail of what type of products will be made. A brief background)

Schedule C: Details of benefit sharing mutually agreed and delivery mechanism

(Please provide detail the detail of what type of benefits)

Form VIII: Certificate of Compliance

Reference No_____ Date ___, ___, ___

Certificate of Compliance to the ABS legislation in Bhutan

This is to certify that _____has legitimately accessed the following genetic resources and/ or associated traditional knowledge in accordance to the Access and Benefit Sharing regime of Bhutan fulfilling the requirement of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT).

Name of the genetic resources and/ or associated traditional knowledge:
Name of the provider of the genetic resources and/ or associated traditional knowledge:
Purpose of access:
Name of the contract agreement:
Reference number of the contract agreement:

This certificate is issued as the evidence of certificate of compliance to the Biodiversity Act of Bhutan, 2022 and is not a substitute for other permits or clearances required under other laws in force in the country.

(Signature and Seal)
National Focal Point

Form IX: Application form for Material Transfer Agreement

Application form for Material Transfer Agreement

Section 1. Details of the User

Name: _____

Address: _____

Works Tel _____ Home Tel _____

E-mail address: _____

Mobile: _____

Section 2. Purpose (*tick the relevant box***)**

□ specific academic research □ exchange of samples

□ sample testing □ others (specify)

Section 3: Details of the Genetic Resources

1. Scientific description of genetic resources: …….

a. If it is for academic research:

i) name of the university: …….
ii) name of the institution: …….
iii) location of the institution: …….
iv) name of the supervisor: …….
v) purpose of the study: …….
vi) affidavit from the institution affirming that it shall not be put to commercial use.

b. If it is for exchange of samples:

i) name of the institution providing the genetic resources: ……..
ii) name of the institution receiving the genetic resources: ……..
iii) location of the institution: …….
iv) affidavit from the institution affirming that it shall not be put to commercial use.

c. If it is for sample testing:

i) purpose of the testing: …….
ii) name of the laboratory: ……...
iii) location of the laboratory: ……...
iv) affidavit from the user affirming that it shall not be put to commercial use.

Section 4. Declaration

The undersigned, being duly authorized representatives, declare to the best of my knowledge and belief that the information contained in this application is correct and complete and I authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application. In case the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed: _____

Date: _____

Name:_____

In the capacity of: _____

Form X: Application for Standard Material Transfer Agreement

Application form for Standard Material Transfer Agreement

Section 1. Details of the User

Name: _____
Address: _____
Works Tel _____ Home Tel _____
E-mail address: _____
Mobile: _____
Membership to ITPGRFA: □ Yes □ No

Section 2. Purpose:

……

Section 3: Details of the Genetic Resources

1. Scientific description of genetic resources:
   - Scientific name:
   Common name:
   Cultivar/Land Races:

a. If it is for academic research:
   i) name of the university: …….
   ii) name of the institution: ……
   iii) location of the institution: ……
   iv) name of the supervisor: …….
   v) purpose of the study: …….
   vi) affidavit from the institution affirming that it shall not be put to commercial use.

b. Sample testing for non-commercial breeding for food security.
   i) purpose: …….
   ii) Name of the institution: …….
   iii) name of the laboratory: ……
   iv) location of the laboratory: ……...
   v) affidavit from the user affirming that it shall not be put to commercial use:

Section 4. Declaration

I/We, the undersigned, being duly authorized representative, declare to the best of my/our knowledge and belief that the information contained in this application is correct and complete and I/We authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application. In case the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed: _____
Date: _____
Name:_____
In the capacity of: _____

Form XI: **SAMPLE TRANSFER CERTIFICATE**

SAMPLE TRANSFER CERTIFICATE
(Certificate of Origin for Genetic Resources)

Reference No_____ Date ___, ___, ___

This Certificate is issued pursuant to regulation 93 of the Biodiversity Rules and Regulations of Bhutan 2023.

_____(Name) is permitted to transfer _____(genetic material) accessed from _____(Dzongkhag), Bhutan to _____(Place of Destination).

The details of the material are as follows:

Material Description:
Quantity of Material to be transferred:
Purpose of transfer:
Name of the contract agreement:
Reference number of the contract agreement:

This Certificate is valid for one time transfer of the genetic resources only.

(Signature and Seal)
National Focal Point